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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/594,339 | 09/27/2006 | Tomoyuki Nakamura | 2006_1605A | 1266 |
| 513 7590 05/07/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021 | | | | |
| EXAMINER | | | | |
| SWOPE, SHERIDAN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1652 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,339

Applicant(s)

NAKAMURA ET AL.

Examiner

SHERIDAN SWOPE

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 29 and 33-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27, 29 and 33-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-27, 29, and 33-46 are pending.

Priority

It is acknowledged that the Office has received Applicants' Foreign Priority Document, JP 2004-096685. If Applicants wish to perfect their claim to priority to JP 2004-096685, an English-language translation should be filed.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1, 2, and 35 drawn to a DANCE polypeptide fragment.

Group II, Claims 3, 4, and 36 drawn to a polynucleotide encoding a DANCE polypeptide fragment.

Group III, Claims 5, 6, 14, 37, and 42 in part, drawn to a DANCE polypeptide.

Group IV, Claims 7, 8, 15, 38, 40, 41, and 42 in part, drawn to a polynucleotide encoding a DANCE polypeptide.

Group V, Claims 9 and 39, drawn to a method of cleaving a DANCE polypeptide.

Group VI, Claims 10, 11, 13, and 43-46 drawn to an antibody to a DANCE polypeptide or fragment.

Group VII, Claim 12, drawn to a method of measuring the amount of cleave DANCE polypeptide.

Group VIII, Claims 16-19, drawn to a DANCE polypeptide complex.

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Group IX, Claims 20-21, drawn to a method of preparing a DANCE polypeptide complex.

Group X, Claims 22-24 and 29, drawn to a screening method for identifying modulators of a DANCE-specific protease.

Group XI, Claims 25-27, drawn to method for identifying modulators of DANCE complex formation.

Group XII, Claim 33, drawn to a kit comprising a DANCE polypeptide.

Group XIII, Claim 34, drawn to a method for identifying a cell expressing a DANCE-specific protease.

For each of Inventions I-XIII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-XIII and one or more of Inventions (A)-(YY), as indicated.

If Group I is elected, elect one of:

- (A.) SEQ ID NO: 6
- (B.) SEQ ID NO: 10
- (C.) SEQ ID NO: 14

If Group II is elected, elect one of:

- (D.) SEQ ID NO: 5
- (E.) SEQ ID NO: 9
- (F.) SEQ ID NO: 13

If Group III is elected, elect one of:

- (G.) SEQ ID NO: 8
- (H.) SEQ ID NO: 12
- (I.) SEQ ID NO: 16
- (J.) A mutant having protease resistance

If Group III is elected, elect one of:

- (K.) lysyl oxidase binding activity
- (L.) lysyl oxidase-like-1 binding activity
- (M.) LTBP1 binding activity

If Group IV is elected, elect one of:

- (N.) SEQ ID NO: 7
- (O.) SEQ ID NO: 11
- (P.) SEQ ID NO: 15
- (Q.) Encoding a mutant DANCE having protease resistance

If Group VI is elected, elect one of:

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- (R.) SEQ ID NO: 6
- (S.) SEQ ID NO: 10
- (T.) SEQ ID NO: 14
- (U.) SEQ ID NO: 8
- (V.) SEQ ID NO: 12
- (W.) SEQ ID NO: 16

If Group VIII is elected, elect one of:

- (X.) Normal DANCE
- (Y.) Mutant DANCE

If Group VIII is elected, elect one of:

- (Z.) Homocomplex
- (AA.) Heterocomplex

If Group VIII is elected, elect one of:

- (BB.) Without lysyl oxidase or LTBP2
- (CC.) With lysyl oxidase
- (DD.) With LTBP2
- (EE.) With lysyl oxidase and LTBP2

If Group IX is elected, elect one of:

- (FF.) Normal DANCE
- (GG.) Mutant DANCE

If Group IX is elected, elect one of:

- (HH.) Homocomplex
- (II.) Heterocomplex

If Group IX is elected, elect one of:

- (JJ.) Without LTBP2
- (KK.) With LTBP2

If Group X is elected, elect one of:

- (LL.) Biochemical assay
- (MM.) Cellular assay
- (NN.) In vivo assay

If Group XI is elected, elect one of:

- (OO.) Normal DANCE
- (PP.) Mutant DANCE

If Group XI is elected, elect one of:

- (QQ.) Homocomplex
- (RR.) Heterocomplex

If Group XI is elected, elect one of:

- (SS.) Without LTBP2
- (TT.) With LTBP2

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If Group XII is elected, elect one of:

- (UU.) A second, distinct DANCE protein
- (VV.) An expression vector encoding a second, distinct DANCE protein
- (WW.) LTBP2
- (XX.) An expression vector encoding LTBP2
- (YY.) One specific combination of (UU)-(XX)

The inventions listed as Groups I-XIII(A-YY) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons. The technical feature linking Groups I-XIII(A-YY) appears to be that they all relate to DANCE polypeptides. However, DANCE polypeptides were well known in the art. Moreover, Nakamura et al, 1999 (IDS) teach an antibody that recognizes cleaved DANCE polypeptide (pg 22477, para 4), which anticipates Claim 13. Therefore Groups I-XIII(A-YY) share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups I-IV, VI, VIII, and XII do not share a special common structural and functional feature while, the methods of Groups V, VII, IX-XI, and XIII do not use the same reagents or produce the same results. In addition, the methods of Groups V, VII, IX-XI, and XIII do not comprise all of the methods for making or using the products of Groups I-IV, VI, VIII, and XII. Accordingly, Groups I-XIII(A-YY) are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action lack a special technical feature for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/

Primary Examiner, Art Unit 1652